CENTERS for MEDICARE & MEDICAID SERVICES

SUMMARY REPORT

DME PUBLIC MEETING

May 13, 2002

INTRODUCTION AND OVERVIEW

Tom Hoyer, Director, CMS' Chronic Care Policy Group, welcomed participants to the Durable Medical Equipment (DME) public meeting. Mr. Hoyer offered opening remarks regarding the increasing importance of HCPCS coding; the increasing need for codes relative to innovations in science and engineering; and regarding the public meetings as a new forum for the public participation we need to assign codes.

David Clark, Director, CMS Office of Professional Relations moderated the meeting. Approximately 36 people attended. There were 5 items on the agenda.

A general overview of the DME public meeting process and related requirements under the Benefits Performance and Improvement Act (BIPA) 2000 was provided.

The DME public meetings meet the BIPA requirements by permitting public consultation for coding and payment determinations for new DME, as explained in the Federal Register Notice published on November 23, 2001.

At these meetings, interested parties will be allowed the opportunity to make oral presentations and submit written comments regarding coding and pricing recommendations for new DME that have been submitted using the HCPCS coding modification process.

The process for development of agendas and speaker lists for the DME public meetings is explained in detail on the CMS HCPCS web site at: www.hcf.gov/medicare/hcpcs.htm

Before the public meeting, the CMS HCPCS workgroup met to review the coding requests on the meeting agenda and to make a preliminary coding recommendation. CMS also made a preliminary recommendation regarding the applicable payment category and the methodology that will be used to set a payment amount for the items on the agenda. These recommendations were presented at the DME public meeting.

AGENDA ITEMS

Agenda Item # 1 - Request #02.47 - to establish codes for bronchial drainage assist device, air pulse generator with connecting hoses and inflatable vest.

Kaye Riley, CMS HCPCS Coordinator, presented an overview of the HCPCS workgroup preliminary coding recommendation to the National Panel to establish the following codes:

E???? High Frequency chest wall oscillation air-pulse generator system, (includes hoses and vest).

A???1 High Frequency chest wall oscillation system vest, replacement, for use with patient owned equipment, each

A???2 High Frequency chest wall oscillation system hose, replacement, for use with patient owned equipment, each

And to discontinue private sector codes S8205 and S8200.

Joel Kaiser of CMS provided an educational overview of variety of methods used for setting the payment amount for items, and when the different methods are used. This overview was also provided as a written attachment to the agenda, and it is attached to this meeting summary. For additional information, the DME payment rules are located at Section 1834 (a) of the Social Security Act.

Joel provided a technical overview of the recommended methodology for use in setting the payment amount for the bronchial drainage assist device, air pulse generator with connecting hoses and inflatable vest. Code E???? falls under the DME fee schedule payment category for capped rental items. If covered, payment would be made on a rental basis. Codes A???1 and A???2 would fall under the DME fee schedule payment category for inexpensive or other routinely purchased items. If covered, payment would be made on a purchase or rental basis. The fee schedule amounts would be gap-filled by the DMERCs.

Maggie Thompson, RN, of Advanced Respiratory, Inc., provided a presentation about the indications and efficacy of the bronchial drainage system while Jim Hanton, also of Advanced Respiratory, Inc., demonstrated the device. Ms. Thompson and Mr. Hanton indicated that Advanced Respiratory, Inc. is pleased with CMS' preliminary recommendation to the HCPCS National Panel. Ms. Thompson and Mr. Hanton responded to questions related to the product regarding contraindications, and whether the effect of the product on diastolic filling of the heart had been studied. Then meeting participants heard testimonials from Dr. Caro Luhrs, M.D. and Mr. Don Muse, as to the effect of the system in the treatment of bronchiectasis and Niemann-Pick disease, based on their experience with use of the system either personally, or by a family member.

Agenda Item # 2 - Request # 02.48 – to establish codes for spring hinge wheelchair shock absorbers.

Kaye Riley, CMS HCPCS Coordinator, presented an overview of the HCPCS workgroup preliminary coding recommendation to the HCPCS National Panel, to establish the following 4 codes:

E???1 Shock absorber for manual wheelchair, each

E???2 Shock absorber for power wheelchair, each

E???3 Heavy duty shock absorber for heavy duty or extra heavy duty manual wheelchair, each

E???4 Heavy duty shock absorber for heavy duty or extra heavy duty power wheelchair, each

Joel Kaiser of CMS provided a technical overview of the recommended methodology for use in setting the payment amount for the shock absorbers. Codes E???1 - E???4 would fall under the DME fee schedule payment category for inexpensive or other routinely purchased items. If covered, payment would be made on a purchase or rental basis. The fee schedule amounts would be gap-filled by the DMERCs.

Mark Chelgren, of Frog Legs, Inc. provided a presentation about indications for use and benefits of Frog Legs wheelchair shock absorbers, and the percentage of wheelchairs that come with some form of shock absorber. Mr. Chelgren indicated a desire for codes for heavy duty as well as manual chairs, due to the difference in weight.

Agenda Item # 3 - Request # 02.52 – to establish a code for a swing away stump support addition to wheelchair.

Kaye Riley, CMS HCPCS Coordinator, presented an overview of the HCPCS workgroup preliminary coding recommendation to the HCPCS National Panel, to discontinue code K0551 and establish the following code:

E???? RESIDUAL LIMB SUPPORT SYSTEM FOR WHEELCHAIR, EACH

Joel Kaiser of CMS provided a technical overview of the recommended methodology for use in setting the payment amount the swing away stump support. Code E???? would fall under the DME fee schedule payment category for inexpensive or other routinely purchased items. If covered, payment would be made on a purchase or rental basis. The fee schedule amounts would be gap-filled by the DMERCs.

Agenda Item # 4 - Request # 02.66, 02.66B and 02.66C – to establish a code for a full face mask, a face mask cushion, and a nasal mask cushion, for use with Continuous Positive Airway Pressure (CPAP) and bi-level systems.

Kaye Riley, CMS HCPCS Coordinator, presented an overview of the HCPCS workgroup preliminary coding recommendation to the HCPCS National Panel, to establish the following codes:

A???1 FULL FACE MASK USED WITH POSITIVE AIRWAY PRESSURE DEVICE, EACH

(TOS = A,P,R BETOS = D1E COV = C PRICING = 32 Short Description: CPAP FULL FACE MASK)

A???2 FACE MASK INTERFACE, REPLACEMENT FOR FULL FACE MASK, EACH

(TOS = A,-,R BETOS = D1E COV = C PRICING = 32 Short Description: REPLACEMENT INTERFACE FOR FULL FACE MASK)

And discontinue the CMS temporary HCPCS "K" codes K0183, K0184, K0185, K0186, K0187, K0188 and K0189, and establish the following replacement "A" codes:

A???3 NASAL APPLICATION DEVICE USED WITH POSITIVE AIRWAY PRESSURE DEVICE

(TOS = A,P,R BETOS = D1E COV = C PRICING = 32 Short Description: NASAL APPLICATION DEVICE)

A???4 NASAL SINGLE PIECE INTERFACE, REPLACEMENT FOR NASAL APPLICATION DEVICE, PAIR OR SINGLE PIECE INTERFACE (TOS = A,P,R BETOS = D1E COV = C PRICING = 32 Short Description: Nasal pillow or face seal)

A???5 HEADGEAR USED WITH POSITIVE AIRWAY PRESSURE DEVICE (TOS = A,P,R BETOS = D1E COV = C PRICING = 32 Short Description: POS AIRWAY PRESSURE HEADGEAR)

A???6 CHIN STRAP USED WITH POSITIVE AIRWAY PRESSURE DEVICE (TOS = A,P,R BETOS = D1E COV = C PRICING = 32 Short Description: POS AIRWAY PRESSURE CHINSTRAP)

A???7 TUBING USED WITH POSITIVE AIRWAY PRESSURE DEVICE (TOS = A,P,R BETOS = D1E COV = C PRICING = 32 Short Description: POS AIRWAY PRESSURE TUBING)

A???8 FILTER, DISPOSABLE, USED WITH POSITIVE AIRWAY PRESSURE DEVICE

(TOS = A,P,R BETOS = D1E COV = C PRICING = 32)

A???9 FILTER, NON DISPOSABLE, USED WITH POSITIVE AIRWAY PRESSURE DEVICE (TOS = A,P,R BETOS = D1E COV = C PRICING = 32 Short Description: FILTER, NON DISPOSABLE W PAP

Joel Kaiser of CMS provided a technical overview of the recommended methodology for use in setting the payment amount for the swing away stump support. Codes A???1 through A???9 would fall under the DME fee schedule payment category for inexpensive or other routinely purchased items. If covered, payment would be made on a purchase or rental basis. The fee schedule amounts for codes A???1 and A???2 would be gap-filled by the DMERCs. The fee schedule amounts for codes A???3 through A???9 will be cross-walked from codes K0183 through K0189, respectively.

Dr. Nicholas Hill and Mr. Ron Richard provided a presentation on the products on behalf of the ResMed Corporation. Dr. Hill provided a clinical presentation about indications for the Oro-nasal vs. the nasal mask. Mr. Richard presented information concerning the percentage of use of nasal vs. full face masks, and the use of nasal mask cushions and pillows. Mr. Richard responded to a number of questions regarding justification of separate codes for nasal cushions and pillows, regarding whether the new code language adequately described both, and whether the purpose of both is the same. Mr. Richard indicated a desire for a separate code for nasal cushions, and a need to clarify confusion that may be a result of language used in the current codes.

Agenda Item # 5 - Request # 02.70 and 02.70B – to establish a code to identify a Monochromatic Near Infrared Energy system, and flexibly therapy pads.

Kaye Riley, CMS HCPCS Coordinator, presented an overview of the HCPCS workgroup preliminary coding recommendation to the HCPCS National Panel, to retain the existing wording in the description for the device category – E0221 INFRARED HEATING PAD SYSTEM

And to establish the following DME accessory code:

A???? REPLACEMENT PAD FOR INFRARED HEATING PAD SYSTEM, EACH

Joel Kaiser of CMS provided a technical overview of the recommended methodology for use in setting the payment amount for the flexibly therapy pads Code A???? would fall under the DME fee schedule payment category for inexpensive or other routinely purchased items. If covered, payment would be made on a purchase or rental basis. The fee schedule amounts would be gap-filled by the DMERCs.

Mr. Craig Turtzo of Anodyne Therapeutics provided a presentation on the indications and effects of infrared heat therapy, and the difference, in terms of energy delivery, between the current product and its predicate device, coded at E0221. Mr. Turtzo responded to a number of questions from meeting participants, such as requests to describe the difference between this and other heat treatment products, such as the "Warm-Up".

Stuart Goldman, D.P.M. provided a testimonial regarding his experience in using Anodyne's system and pads and the temporary effects he has seen in his patients as a result of the treatment.

CLOSING REMARKS

In light of new information provided at the DME public meetings, the HCPCS workgroup will reconsider its preliminary coding recommendations, CMS staff will reconsider payment methodology recommendations, and the workgroup will formulate its final recommendation to the HCPCS National Panel. By November 15, 2002, the HCPCS Coordinator will mail letters to every requestor of a HCPCS coding change, notifying them of the National Panel's decision. The HCPCS Level II annual update, including any coding changes, will be effective January 1st 2003.

There will be 1 more DME public meeting this year. It will be held on June 17th in the CMS Auditorium. Agendas and Summaries for the DME public meetings can be found, and on-line registration can be completed, at the CMS HCPCS web site at:

www.hcfa.gov/medicare/hcpcs.htm

Cindy Hake of CMS thanked the participants for their very valuable input at the meeting; for sharing their ideas regarding getting the word out about this new forum; and for their helpful suggestions regarding where emphasis and clarification are needed in our information concerning DME public meeting process and participation.

Attachment to May 14, 2002 DME Public Meeting Summary

Payment for Durable Medical Equipment (DME)

Section 1834(a) of the Social Security Act (the Act) requires that payment for DME furnished on or after January 1, 1989, be made on the basis of fee schedules. Prior to January 1, 1989, payment for DME was made on the basis of the reasonable charge methodology. For purposes of establishing the DME fee schedule, section 1834(a) of the Act separates DME into the following payment categories, each with its own unique payment rules:

- Inexpensive and other Routinely Purchased Items
- Frequently Serviced Items
- Oxygen and Oxygen Equipment
- Capped Rental Items

There is also a payment category for customized items. The carriers determine the payment amount for purchase of each customized item. These payment categories are described at the end of this document.

Section 1834(a) of the Act requires that statewide fee schedule amounts be established based on average reasonable charges made during a base period from 1986 to 1987, increased by 1.7 percent to arrive at 1989 ("base") fee schedule amounts. The specific months from 1986 to 1987 that are used to calculate the statewide fee schedule amounts vary by payment category. The fee schedule amounts are updated on an annual basis by a factor legislated by Congress. In addition, the fee schedule amounts are limited by a national ceiling (upper limit), equal to the median of the statewide fee schedule amounts, and a national floor (lower limit), equal to 85 percent of the median of the statewide fee schedule amounts.

Because reasonable charge data from 1986-87 does not exist for new DME items, the carriers must "gap-fill" the base fee schedule amounts for these items using a methodology provided in section 5101.2.A of the Medicare Carriers Manual. This section instructs the carriers to gap-fill using:

- the fee schedule amounts for comparable equipment,
- calculated fee schedule amounts from a neighboring carrier, or
- supplier price lists.

As a substitute for supplier price lists when they are not available, the carriers may gap-fill the base fee schedule amounts using the manufacturer's suggested retail prices or wholesale prices plus a markup.

The gap-filling methodology is used to approximate historic reasonable charges from 1986 to 1987 when historic data are not available. This gap-filling methodology has been in use since 1989, the initial year of the DME fee schedules. If neither reasonable charge data or prices lists from 1986-87 are available and more current prices are used, the carriers are instructed to decrease the more current prices by a "deflation" factor in order to approximate the 1986/1987 base year price for gap-filling purposes. The deflation factors are equal to the percentage change in the consumer price index for all urban consumers (CPI-U) from the mid-point of the fee schedule base period (1986/87) to the mid-point of the year in which the retail price is in effect (e.g. 2001). After deflating the prices, the carriers will increase the prices by 1.7 percent to arrive at 1989 base fee schedule amounts.

The carriers then submit the 1989 base fee schedule amounts to CMS. To set the final fee schedule amounts, CMS applies all of the annual update factors that have occurred since 1989 to these base amounts and calculates the national ceiling and floor limits. The final fee schedule amounts are then transmitted to the carriers and fiscal intermediaries for implementation.

DME PAYMENT CATEGORIES

INEXPENSIVE AND OTHER ROUTINELY PURCHASED ITEMS

- Section 1834(a)(2) of the Act
- Fee Schedules: Purchase (new); Purchase (used); Rental (monthly)
- Fee Schedule Base Period: July 1, 1986 through June 30, 1987

Items that have a purchase price of \$150 or less, are generally purchased 75 percent of the time or more, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or intermittent assist device with continuous airway pressure device. Total rental payments cannot exceed the purchase (new) fee for the item.

FREQUENTLY SERVICED ITEMS

- Section 1834(a)(3) of the Act
- Fee Schedules: Rental (monthly)
- Fee Schedule Base Period: July 1, 1986 through June 30, 1987

Items that require frequent and substantial servicing. Examples of such items are provided in section 1834(a)(3)(A) of the Act. These items are rented as long as they are medically necessary.

OXYGEN AND OXYGEN EQUIPMENT

- Section 1834(a)(5) of the Act
- Fee Schedules: Monthly Payment Amounts for Stationary Equipment, Oxygen Contents, Portable Oxygen Contents, and Portable Equipment
- Fee Schedule Base Period: January 1, 1986 through December 31, 1986

Monthly payments are made for furnishing oxygen and oxygen equipment. If the beneficiary owns their equipment, a monthly payment is made for oxygen contents only. An additional monthly payment is made for those beneficiaries who require portable oxygen. If the beneficiary owns their portable equipment, then a monthly payment is made for portable contents only.

CAPPED RENTAL ITEMS

- Section 1834(a)(7) of the Act
- Fee Schedules: Rental (monthly), Purchase (power wheelchairs only)
- Fee Schedule Base Period: July 1, 1986 through December 31, 1986

Payment for these items is on a rental basis. However, beneficiaries have the option to take over ownership of these items after the 13th rental payment. The supplier must inform the beneficiary of the "purchase option" in the 10th month of rental. If the beneficiary chooses the rental option, total rental payments may not exceed 15, but the supplier must continue to furnish the item as long as it is medically necessary.

The rental fee for capped rental items for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 15 is equal to 7.5 percent of the purchase fee for the item. Power wheelchairs can be purchased in the first month.

Beginning 6 months after the 15th rental payment is made, suppliers may be paid a semi-annual (every 6 months) maintenance and servicing fee that is not to exceed 10 percent of the purchase fee for the item. For patient owned items, payment for maintenance and servicing is made as needed.

CERTAIN CUSTOMIZED ITEMS

- Section 1834(a)(4) of the Act

Payment is made in a lump-sum amount for the purchase of the item in a payment amount based on the carrier's individual consideration for that item.